K072568
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OCT 5 " 2007

Special 510(k) Summary:
Line Extension to the Stryker Spine OASYS™ System

Proprietary Name:	OASYS™ System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class II 21 CFR 888.3070 (b)(1): Pedicle Screw Spinal System 21 CFR 888.3050: Spinal Interlaminal Fixation Orthosis
Device Product Code:	MNI: Orthosis, Spinal Pedicle Fixation KWP: Appliance, Fixation, Spinal Interlaminal
For Information contact:	Simona Voic Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 **Telephone: (201) 760-8145** **Fax: (201) 760-8345** **Email: Simona.Voic@stryker.com**
Date Summary Prepared:	September 11, 2007
Predicate Devices	Stryker Spine's OASYS™ System - 510(k)#: K032394, K052317, & K062853 DePuy Spine, Inc. Summit OCT Spinal System – 510(k)#: K030103 & K041203

Description of Device Modification	This 510(k) adds new polyaxial screw components (non-biased and cancellous styles) to the existing OASYS™ System.
Intended Use	When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput -T3), the Stryker Spine OASYS™ System is intended for • Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) • Spondylolisthesis • Spinal Stenosis • Fracture/Dislocation • Atlanto/axial fracture with instability • Occipitocervical dislocation • Revision of previous cervical spine surgery • Tumors When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine. The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper

	thoracic (C1 -T3) spine. The Stryker Spine OASYS™ System™ can also be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors.
Summary of the Technological Characteristics	The new polyaxial screws of the Stryker Spine OASYS™ System are identical to the existing polyaxial screws of the OASYS™ System with regard to materials, intended use, and basic operating principles. The new polyaxial screws differ from the existing OASYS™ polyaxial screws with regard to specific design features; however, mechanical testing has demonstrated that OASYS™ Systems constructed with the new screws perform equivalently to one or more of the cited predicate device systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Spine
% Ms. Simona Voic
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

OCT 5 ° 2007

Re: K072568
Trade/Device Name: OASYS™ System
Regulation Number: 21 CFR §888.3070
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: Class II
Product Code: KWP, MNI
Dated: September 11, 2007
Received: September 12, 2007

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072568

Device Name: _ Line Extension to the Stryker Spine OASYS™ System

Indications for Use:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput -T3), the Stryker Spine OASYS™ System is intended for:

- Degenerative Disc Disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Spinal Stenosis
- Fracture/Dislocation
- Atlanto/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

When used with the occipital plate, the bone screws are limited to occipital fixation only. The bone screws are not intended to be used in the cervical spine.

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1 -T3) spine.

The Stryker Spine OASYS™ System™ can also be linked to the Xia® System, SR90D System and Xia® 4.5 Spinal System via the rod-to-rod connectors.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072568